UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,186	03/23/2004	Milan Graovac	13180-30	2024

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EXAMINER
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ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

PTOL-90A (Rev. 04/07)

		Application No.	**Applicant(s)**
Office Action Summary		10/806,186	GRAOVAC ET AL.
		Examiner	**Art Unit**	
		Jeffrey G. Hoekstra	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>02 October 2007</u>.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1,3 and 5-21</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>1,3 and 5-21</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on <u>23 March 2004</u> is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1.   A request for continued examination under 37 CFR 1.114, including the fee set

forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this

application is eligible for continued examination under 37 CFR 1.114, and the fee set

forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action

has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on

10/02/2007 has been entered.

Notice of Amendment

2.   In response to the amendment filed on 10/02/2007, amendment(s) to the

specification, and amended claim(s) 1, 7, 10, 13-17, and 19-21. The current rejections

of the claim(s) 1, 3, and 5-21 is/are *withdrawn*. The following new and reiterated

grounds of rejection are set forth:

Claim Objections

3.   Claim 1 is objected to because of the following informalities: the positive

recitation of "the possibility" in line 1 should apparently read "a possibility. Appropriate

correction is required.

4.   Claim 1 is objected to because of the following informalities: the positive

recitation of "the sum" in line 17 should apparently read "a sum". Appropriate correction

is required.

5.   Claim 3 is objected to because of the following informalities: the positive recitation of "the measure electrical property" in line 2 should apparently read "the measured electrical property". Appropriate correction is required.

6.   Claim 11 is objected to because of the following informalities: the positive recitation of "in the step of obtaining a baseline electrical property" in lines 1-2 should apparently read "in the step of using a model of the body part to obtain the baseline electrical property". Appropriate correction is required.

7.   Claim 12 is objected to because of the following informalities: the positive recitation of "applying a plurality of electrodes to the body part; and obtaining the measured electrical property of the body part with the plurality of electrodes" in lines 2-4 should apparently read "applying the electrode array to the body part; and obtaining the measured electrical property of the body part with the electrode array". Appropriate correction is required.

8.   Claims 14 and 16 are objected to because of the following informalities: the positive recitation of "wherein the step of obtaining the baseline electrical property includes" in lines 1-2 should apparently read "wherein the step of using a model to obtain the baseline electrical property includes", "wherein the measured electrical property is obtained by", or the like. Appropriate correction is required.

9.   Claims 20 and 21 are objected to because of the following informalities: the positive recitation of "a possibility" should apparently read "the possibility. Appropriate correction is required.

Claim Rejections - 35 USC § 112

10.   The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly
> claiming the subject matter which the applicant regards as his invention.

11.   Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite

for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention.

12.   Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete

for omitting essential structural cooperative relationships of elements, such omission

amounting to a gap between the necessary structural connections. See MPEP

§ 2172.01. The omitted structural cooperative relationships are: the relationship

between "using a model of the body part" and "obtain[ing] a baseline electrical property".

The scope of the claim with regards to the relationship between "using a model of the

body part" and "obtain[ing] a baseline electrical property" is indeterminate. As claimed,

the omitted cooperative relationship between the "using a model of the body part" and

the "obtain[ing] a baseline electrical property" raises the question of how "using a model

of the body part" "obtain[s] a baseline electrical property" and renders the claim

indefinite.

Claim Rejections - 35 USC § 103

13.   The text of those sections of Title 35, U.S. Code not included in this action can

be found in a prior Office action.

14.   Claims 1, 3, and 5-21 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Shmulewitz et al (US 6,095,987) in view of Clay et al (IDS Non-Patent Literature,

Cite 1: IEEE Transactions on Medical Imaging, Vol. 21, No. 6, June 2002) and in further

view of Jersey-Willuhn et al (US 2003/0216630 A1).

15.   Shmulewitz et al teaches disease diagnosing bioimpedance analysis methods

including the following:

16.   For claims 1, 3, and 7-9, Shmulewitz et al teaches disease diagnosing

bioimpedance analysis methods, comprising:

- representing a body part, as i numbers of "compartments" as in Equation (2) in

    column 6, with a grid having a plurality of finite elements (column 6 line 30 – column

    7 line 9);

- obtaining a set of weights, W_i as in Equation (2) in column 6, associated with a

    particular one of the plurality of finite elements using a model of the body part

    (column 6 line 30 – column 7 line 9);

- computing a diagnostic, $I(t)$ as in Equation (2) in column 6, at the particular finite

    element, the diagnostic being a function of the set of weights, and a measured

    electrical property obtained with an electrode array (column 5 lines 43-65);

- utilizing the diagnostic (column 16 line 23 – column 17 line 26) to diagnose the

    possibility of disease in the body part; and

- obtaining a baseline electrical property, a conditioned impedance value (column 7

    lines 46-63), associated with the body part using a model, a control subject, or a

    finite element method (column 6 lines 50-64) thereof, wherein the diagnostic, $I(t)$ as

in Equation (2) in column 6, is a function of the baseline electrical property, the set of weights, and the measured electrical property obtained with the electrode array.

17. For claims 10-11, Shmulewitz et al teaches disease diagnosing bioimpedance analysis methods, wherein the baseline electrical property (column 7 lines 46-63) is obtained assuming non-uniform resistivity (column 4 lines 24-36) by obtaining a baseline voltage and using the baseline voltage to compute a baseline impedance (column 8 lines 57-67).

18. For claims 12-14, Shmulewitz et al teaches disease diagnosing bioimpedance analysis methods, further comprising:

- applying a plurality of electrodes to the body part (column 5 lines 44-66);

- obtaining a measured electrical property of the body part with the plurality of electrodes (column 5 lines 44-66);

- wherein the step of applying includes applying current through each set of current injection electrode pairs on the body part and applying voltage measurement through each set of electrode pairs on the body part, wherein each of the current injection electrode pairs is associated with one of voltage measurement electrode pairs (column 5 lines 44-66 and column 8 line 57 – column 9 line 16); and

- wherein said step (g) further comprises starting the current injection process with one first pair of injecting electrodes and applying voltage measurement through one first pair of voltage measuring electrodes and repeating this process through i numbers of electrode pairs to obtain a measured impedance (column 5 lines 44-66 and column 8 line 57 – column 9 line 16).

19.   For claims 15-21, Shmulewitz et al teaches the claimed disease diagnosing bioimpedance analysis methods, including: (a) weighting measured and calculated electrical parameters associated with electrode pairs and (b) using the body part model to obtain a set of baseline impedances associated with electrode pairs.

20.   However for claims 1, 3, and 5-21, Shmulewitz et al teaches the claimed disease diagnosing bioimpedance analysis methods as aforementioned, *except* for expressly disclosing: (a) using the body part model to obtain a set of current densities, (b) calculating an average of the diagnostic function both as a global average and as an average of the diagnostic computed at each finite element, (c) calculating a second averaged diagnostic correlated to a homologous body part, (d) expressing the diagnostic function in terms of an individual finite element as a calculated individual impedance divided by the measured individual impedance, (e) calculating the difference or difference divided by the averaged diagnostics between first and second averaged diagnostics to indicate the possibility of disease in the body part or homologous body part, and (f) the grid is a two- or three- dimensional. Clay et teaches disease diagnosing bioimpedance analysis methods including (a) using the body part model to obtain a set of current densities (page 630 parts II.A. and II.C.), (b) calculating an average of the diagnostic function both as a global average and as an average of the diagnostic computed at each finite element (page 631 equation 8), (c) calculating a second averaged diagnostic correlated to a homologous body part (page 634 part D and Figure 3), (d) expressing the diagnostic function in terms of an individual finite element as a calculated individual impedance divided by the measured individual

impedance via weighting (page 632 equation 18), (e) calculating the difference or

difference divided by the averaged diagnostics between first and second averaged

diagnostics (Tables I-IV) to indicate the possibility of disease in the body part or

homologous body part, and (f) a grid having a plurality of finite elements in either two or

three dimensions (page 630 Part II.B. and page 636 Part IV.). All the claimed elements

were known in the prior art and one skilled in the art could have combined the elements

as claimed by known methods with no change in their respective functions, and the

combination would have yielded predictable results to one of ordinary skill in the art at

the time of the invention. All of the component parts are known in Shmulewitz et al and

Clay et al. The only difference is the combination of the component parts into a single

device. Thus, it would have been obvious to one having ordinary skill in the art at the

time of the invention to combine the components as taught by Shmulewitz et al with the

components as taught by Clay et al to achieve the predictable results of configuring a

bioimpedance analysis method to diagnose disease via utilizing known finite element

calculation methods.

21.   Thus for claims 1, 3, and 5-21, Shmulewitz et al in view of Clay et al disclose the

claimed invention except for expressly disclosing using a model of the body part to

obtain a baseline electrical property associated with each of the plurality of finite

element for each of a plurality of current injections obtained with an electrode array.

Jersey-Willuhn et al teaches diagnosing bioimpedance analysis methods (abstract)

including using a model of the body part to obtain a baseline electrical property

associated with each of the plurality of finite element for each of a plurality of current

injections obtained with an electrode array (paragraphs 26, 30, 89, 93, 103-112, 161-170, 176-178, 185-195, and 204-205). All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Shmulewitz et al in view of Clay et al and Jersey-Willuhn et al. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Shmulewitz et al in view of Clay et al with the components as taught by Jersey-Willuhn et al to achieve the predictable results of configuring a bioimpedance analysis method to diagnose disease via utilizing known finite element calculation methods.

Response to Arguments

22.   Applicant's arguments with respect to claims 1, 3, and 5-21 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./
Jeff Hoekstra
Examiner, Art Unit 3736